K081111

510(K) Summary
Smith & Nephew Legion Hinge Knee

JUL 23 2008

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 East Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6017
CONTACT PERSON:	Nicholas B. Tabrizi
DATE SUMMARY PREPARED:	April 15, 2008
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew Legion Hinge Knee
COMMON OR USUAL NAME:	Total Knee Joint
CLASSIFICATION NAME:	Prosthesis, Knee, Femorotibial Constrained, Cemented,Metal/Polymer
DEVICE CLASS:	Class II
PANEL CODE:	Orthopaedics/87/KRO

A. INTENDED USE:

This system is to be used to treat gross knee instability resulting from loss of collateral ligament function, gross bone loss possibly including the insertion points of the collateral ligaments or patella tendon, or comminuted fractures of the proximal tibia or distal femur. Patients requiring hinged knees typically fall into one of four categories; 1) revision knee procedure 2) oncology 3) trauma or 4) severe varus/valgus primary knees.

B. INDICATIONS FOR USE:

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained and hinge knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

The Legion Hinge Knee System is for Cemented Use Only.

C. DEVICE DESCRIPTION:

Subject of this pre-market notification is the LEGION Hinge Knee system. This is an extension to the LEGION Revision system. This system broadens the complexity of cases which can be addressed with LEGION by offering a hinged option which can be used in cases of inadequate ligament stability of the knee or gross femoral/tibial bone loss. Instrumentation is to be minimized by using many of the LEGION Revision instruments. This system is to include femoral and tibial revision components, tibial inserts, distal femoral and proximal tibial segments, stems, cones and wedges as well as the instruments and trials required to implant the components. The tibial component includes a rotating platform option.

D. SUBSTANTIAL EQUIVALENCE INFORMATION:

The Smith & Nephew Legion Hinge Knee is similar to the following commercially available devices regarding design features, overall indications, materials, sterilization and manufacturing:

Manufacturer	Description	510(K)	Clearance Date
Biomet	Orthopaedic Salvage System (OSS)	K02757	11/24/2000
Plus Orthopedics AG	RT PLUS Solution System	K023667	12/24/2000
Zimmer	Nexgen Complete Knee Solution Rotating Hinge Knee	K013385	1/9/2002

E. SUMMARY OF TECHNOLOGICAL COMPARISON:

The intended use, design, and materials of the Smith & Nephew Legion Hinge Knee are substantially equivalent to the systems listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2008

Smith & Nephew, Inc.
Orthopaedic Division
% Mr. Nicholas B. Tabrizi
Regulatory Affairs Specialist II
1450 East Brooks Road
Memphis, TN 38116

Re: K081111
Trade/Device Name: Smith & Nephew Legion Hinge Knee System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: April 15, 2008
Received: April 24, 2008

Dear Mr. Tabrizi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

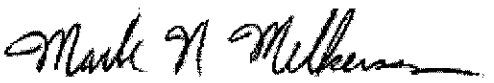
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081111

Device Name: Smith & Nephew Legion Hinge Knee System

Indications for Use:

1. Rheumatoid arthritis.
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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081111